

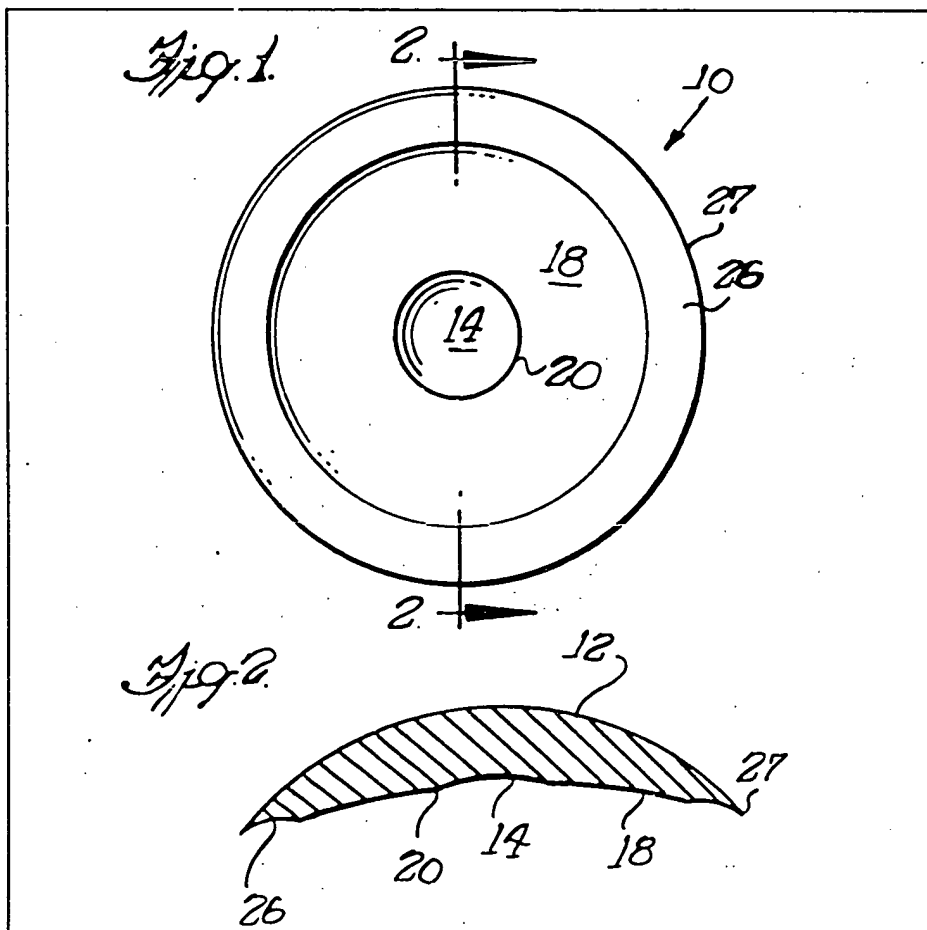
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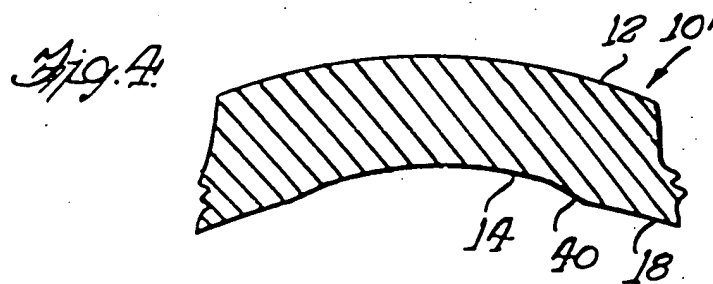
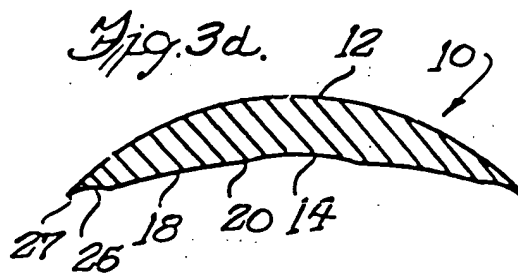
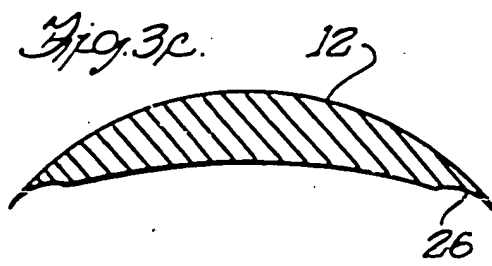
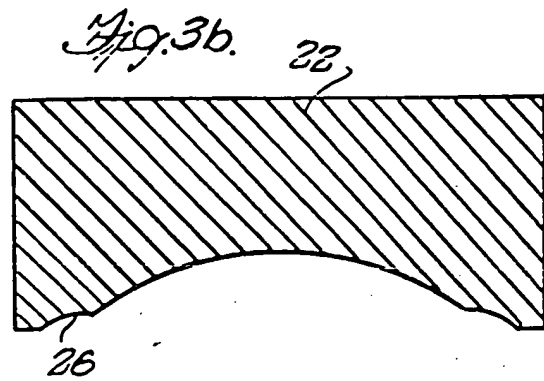
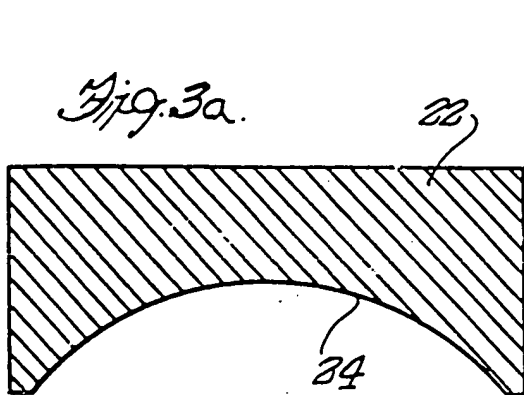
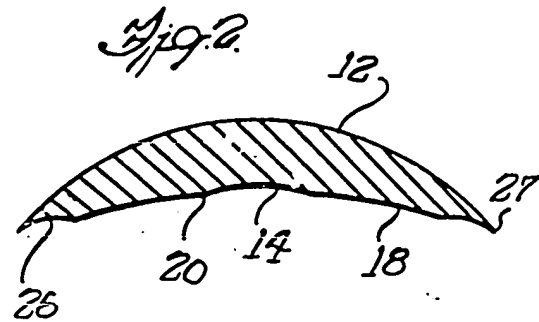
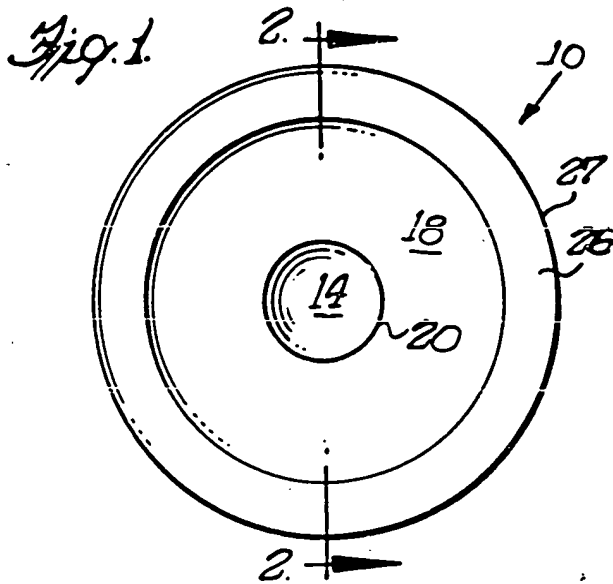
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(54) Improved bivision contact lens for the treatment of presbyopia

(57) A contact lens has an anterior surface 12 and a posterior surface including a central portion 14 less than 2.5 mm. in diameter and greater than 1.0 mm. in diameter which optically cooperates with the anterior surface 12 to provide a correction for distance viewing, and a paracentral portion 18 which optically cooperates with the anterior surface 12 to provide a correction for near viewing.





## SPECIFICATION

### Improved division contact lens for the treatment of presbyopia

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This invention relates to an improvement in contact lens design and more specifically relates to contact lenses designed to correct presbyopia.

#### 10 *Background of the invention*

Contact lenses have been used for the correction of such disorders as myopia, hyperopia, aphakia, and astigmatism. Thus far, contact lenses have been less successful in the treatment of presbyopia which is a defect of vision associated with advancing age characterized by loss of elasticity of the crystalline lenses of the eye. The presbyopic patient lacks visual accommodation, i.e., the ability of an eye to adjust to see clearly objects that are close to or at intermediate distances from the eye without the aid of a suitable corrective lens. Presbyopia often may begin to occur at age forty.

The common correction for presbyopia is to use bifocal eyeglass lenses which have an upper portion ground for distance viewing, having, most commonly, a correction for myopia or hyperopia, and a lower portion with a dioper add for near viewing. This solution is feasible in eyeglasses because, when the eyeball moves down as the patient looks down, the pupil of the eye moves relative to the lens.

A presbyopic patient typically needs about 2.50 additional diopters for reading than for normal distant viewing. For example, a nearsighted (myopic) person with presbyopia might be fitted with bifocal eyeglasses having an upper portion ground to give a -6.00 diopter correction and a lower portion ground to give a -3.50 diopter correction. A farsighted person may have bifocals with an upper portion ground to +4.00 diopter correction and a lower portion ground to a +6.50 diopter correction. If the lenses of the patient's eyes retain sufficient elasticity, the patient, by viewing either through the near or distant portion, will be able to accommodate to see objects clearly at intermediate distances, although sometimes it is necessary that additional viewing portions be provided where the lenses of the patient's eyes are so rigid that very little accommodation is achievable.

The bifocal solution employed in eyeglasses has not lent itself readily to contact lenses. Several types of presbyopic contact lenses have been described and used including division lenses, alternating vision lenses, ballasted lenses and multifocal lenses. Each known type of presbyopic contact lens has certain disadvantages.

A division lens described in U.S. Patent No. 3,037,425 has a central distance viewing portion and a paracentral near viewing portion. The area of the central distance viewing portion has an area equal to about one-half the area of the pupil under ordinary lighting conditions. As described in Mandell, R.B., *Contact Lens Practice*, Charles C. Thomas, publ. Springfield, Illinois (1965) p. 349, half the area of the pupil under normal lighting conditions corresponds generally to 3.0 mm. in diameter. Some blurring or

double imaging invariably occurs when the patient attempts to focus for either near or distance viewing.

In alternating vision bifocal contact lenses which are freely rotatable on the cornea, both a central viewing portion and a paracentral viewing portion are sufficiently large to each, in turn, fully cover the patient's pupil. When the patient looks straight ahead, the contact lens is centered on the eye, and the patient views entirely through the central distance viewing portion, but when the patient looks down, the lens bumps against the lower lid and relocates on the cornea, positioning the paracentral near viewing portion over the pupil. Not only are such alternating vision bifocal contact lenses inconvenient in that they permit only near or distance viewing at any one time, but the need to proportion the lens to engage the lower lid and the precise measurements needed to determine the desired diameters of the bifocal segments make such lenses difficult to fit.

Ballasted contact lenses, like the alternating vision lenses, are relocatable over the pupil of the eye permitting the presbyopic patient to alternately view through near or distance viewing portions, but the lower portion of the lens is ballasted so that instead of rotating, it maintains a predetermined vertical orientation. While the thicker lower portion of the ballasted contact lens provides better contact with the eyelid than does a rotating alternating vision lens, a ballasted lens is heavy, and likewise at any one moment, permits only near or distance vision.

Multifoci lenses for treatment of presbyopia have been used which give a continuous range of diopter values from distance, through intermediate, to near. While considerable success is achieved with many patients fitted with multifoci lenses, other patients have considerable difficulty adjusting to multifoci presbyopic contact lenses. The successful fitting of contact lenses depends not only on the skill of the lens maker, but on the ability of the patient to adjust to the lenses and visually perceive the images entering therethrough. When a patient is fitted with a multifoci contact lens, he is likely, at first, to see clearly only distant objects. The ability to perceive the images entering the intermediate and near viewing portions of the lens often comes only after a period of adjustment, and if the patient is unable or unwilling to submit to this period of adjustment, he cannot be fitted with multifoci lenses.

Improved contact lenses are needed to treat presbyopic patients, particularly those patients for whom prior type lenses are found to be unsuitable.

#### *Summary of the invention*

A contact lens for the treatment of presbyopia has a spherical anterior surface and a posterior surface including a central portion greater than 1 mm. in diameter and less than 2.5 mm. in diameter, the surface of which is spherical and which optically cooperates with the anterior surface to provide a distance correction, and an annular paracentral portion therearound, the surface of which is spherical, and which optically cooperates with the anterior surface to provide a near correction. The limited area of the central portion relative to the paracentral

viewing portion permits simultaneous near and distance vision without blurring or double imaging.

*Brief description of the drawings*

5 *Figure 1* is a plan view of the posterior of a contact lens for the treatment of presbyopia embodying various features of the invention;

*Figure 2* is a cross-sectional view of the contact lens of *Figure 1*; and

10 *Figures 3a-d* illustrate the generation of a contact lens of the present invention.

*Figure 4* is an alternative embodiment of a contact lens in which a distinct viewing portion is provided for intermediate viewing.

15 *Detailed description of the preferred embodiments*

In accordance with the present invention, a contact lens 10 for the treatment of presbyopia, having an anterior spherical curvature 12, and a posterior surface including a central portion 14 with a spherical curvature that cooperates optically with the anterior surface to provide a distance correction, and a paracentral portion 18 with a spherical curvature which cooperates optically with the anterior surface to provide a near correction, permits simultaneous viewing of near and far objects with no blurred or double imaging when the central distance portion is greater than 1 mm. in diameter and less than 2.5 mm. in diameter. In most cases, pinpoint optics provided by the junction 20 of the central and paracentral portions 14, 18 may help the patient to clearly view objects at intermediate distances.

A bivision contact lens 10 according to the present invention is generated according to a prescription which includes the keratometer reading which measures the radius of curvature of the patient's cornea, the measured diopter correction needed for distance vision and the diopter add which the patient requires for near, i.e. reading, viewing. A standard spherical lens button 22 (*Figure 3a*) with a spherical concave posterior surface 24 is selected which has a base radius of curvature matched to the base radius of curvature of the cornea as determined by the keratometer reading.

45 To aid the passage of tears under the lens 10, a bevel or peripheral curve 26 is generated (*Figure 3b*) in the edge of the button 22. The radius of curvature of the bevel 26 is greater than the base curve, and greater than that portion of the cornea over which it lies. Typically, the level 26 is between about 0.3 and 50 1.0 mm. wide.

By standard calculations, primarily depending on the index of refraction of the lens material, a radius of curvature is determined for an anterior surface 12 which will cooperate with the base radius of curvature of the button 22 to provide the desired near viewing correction, and the anterior surface of the desired radius of curvature is generated by standard lathe cutting techniques. The lens is cut to size, i.e., 60 between about 7 and about 10 mm. in diameter, and the edge 27 is contoured and finished.

By a similar calculation, a radius of curvature is determined for the central portion 14 which will cooperate with the anterior surface 12 to provide the 65 required distance viewing correction. With an

appropriate lathe cutting tool, directed axially into the lens 10, the central distance viewing portion 14 is cut (*Figure 3d*) into the posterior surface 24. The lathe cutting is precisely controlled to form a central viewing portion 14 greater than 1 mm. in diameter and less than 2.5 mm in diameter and preferably between 1.5 and 2 mm. in diameter.

70 The anterior surface 12 is polished at any time after it is generated. The junction between the paracentral portion 18 and the bevel 26 may be blended during polishing to remove the sharpness thereof, and the bevel, the paracentral portion 18 and the central portion 14 are each in turn polished with a polishing lap matched to the respective radii of curvature and covered with a fine abrasive-carrying polishing pad. The spherical polishing laps are each directed axially into the posterior of the lens 10, and because the radii of curvature of the bevel 26, paracentral portion 18 and central portion 14 are progressively smaller, each polishing lap touches and polishes only that surface to which it is matched.

Because the base curve of the blank 22 is selected according to the curvature of the cornea, the paracentral portion 18 which remains, substantially unchanged, fits closely against the cornea and provides a good physical fit. A sharp delineation exists between the lesser radius of curvature central portion 14 and the greater radius of curvature paracentral portion 18.

95 In an alternative method of forming a bivision contact lens 10, radii of curvature are calculated for an anterior surface 12, a posterior central portion 14 and a posterior paracentral portion 18 and the lens is formed from a blank having a concave posterior surface with the radius of curvature calculated for the central portion. Using a lathe tool which will generate the formulated paracentral portion, the blank is cut, beginning from the periphery of the posterior surface, inward until only that portion of the original posterior surface remains which will serve as the central distance portion 14 of the lens posterior surface. The bevel 26 and anterior surface 12 are generated, and the lens 10 is polished.

By selecting a radius of curvature for the paracentral portion 18 which matches the base radius of curvature of the cornea and deriving radii of curvature for the anterior surface 12 and the central portion 14 therefrom, the paracentral portion serves the dual role of an optical surface and a fitting surface, and the generation of the lens is thereby simplified. In some cases, for example, when the calculated central, paracentral and anterior radii of curvature would result in a very thick lens, an annular fitting portion beyond a paracentral viewing portion is generated with a distinct radius of curvature. When the radius of curvature of the paracentral viewing surface is not tied to the radius of curvature of the cornea, a great flexibility is available in selecting sets of optical radii of curvatures.

125 The contact lens 10 may be made of any suitable material of which contact lenses are made. Generally, contact lenses are made of hard, semihard, semisoft or soft plastic. Plastics used for lenses should be nonallergenic and nontoxic to the eye, resistant to scratching and breaking, clear and not 130

discolorable over extended periods of time. Government-approved materials for hard contact lenses presently include polymethylmethacrylate, cellulose acetylbutyrate, a combination of polymethylmethacrylate and silicone. Government approval is being sought for hard silicone rubber and, if approved, may be used to make presbyopic contact lenses. However, the invention is not intended to be limited to currently available plastics, and the lenses herein described may be made of any material which is later discovered or approved.

Contact lenses for the correction of presbyopia may also be soft lenses providing that the prescribed radii of curvature can be maintained. Soft contact lenses are commonly made from hydrophilic gel-like plastics which absorb water to varying degrees. At the present state of development of soft lenses, soft lenses with up to about 40 percent water content may retain the prescribed surfaces.

While the bivision lenses 10 of the present invention are similar in most respect to bivision lenses presently produced, the reduction in size of the central portion 14 surprisingly and unexpectedly results in superior optical qualities. Whereas bivision lenses currently available for the treatment of presbyopia cause blurring and double imaging, the bivision lenses 10 herein described provide simultaneous near and distance vision without blurring or double imaging. The term "simultaneous vision" as used herein actually refers to the ability of the patient to adjust generally instantaneously to see both near and far objects just as a nonpresbyopic person adjusts generally instantaneously to view either near or distant objects.

The particular reasons why the bivision lenses 10 with reduced-diameter central portions 14 results in clear simultaneous vision is uncertain, and it is not intended that the invention to be limited to any theory. However, it is believed that the reduced-diameter central portion 14 may cause less "confusion" to the eye which must select those light rays which it perceives.

Heretofore, it was believed that the central distance portion of a bivision contact lens should be about equal to the paracentral viewing portion of the lens so that eye might select, with equal facility, the portion of the equal-area lens through which it perceives an image. Thus for a normal pupil in normal lighting conditions which is typically just over 4 mm. in diameter, a 3 mm. central portion is provided.

It is felt, that a paracentral viewing portion 18 equal in area to the central portion 14 may not, in fact, give the eye equal facility to perceive through either portion of the lens. Generally an individual has a dominant eye, usually the right eye, which focuses on an object, and the other eye follows along to that both eyes focus to the same distance. It is further the natural tendency of the presbyopic dominant eye to focus for distance rather than near viewing. Because the central viewing portion of an equal-area bivision lens is centrally located, the natural tendency for distance viewing is enhanced. Thus, when it is necessary for the eye to select light rays passing through the paracentral portion for near vision, the

eye experiences some "confusion" in attempting to view near objects, and blurring and/or double imaging results.

In the bivision contact lenses 10 of the present invention, the area of the central portion 14 is dramatically reduced. For example, a 2 mm diameter central portion 14 placed over a 4 mm. diameter pupil will cover only one-fourth of the area of the pupil, as compared to prior bivision lenses in which the central portion covers about one-half of the area of the pupil. The smallness of the central distance viewing portion 14 relative to the paracentral near viewing portion 18 tends to equalize the facility of the eye to alternately select the images through the central and paracentral portions and allows the eye to perceive either near or distant objects without "confusion".

An important advantage of the bivision contact lens 10 with a reduced-diameter central portion 14 is the immediate bivision which the contact lens affords the patient. Whenever a patient wears contact lenses for the first time, a period of adjustment has heretofore been needed for the eye to accept the foreign objects and for the eyes to learn to perceive through the new lenses. Often a patient will reject contact lenses as unsatisfactory without sufficient effort to adjust to the lenses. The adjustment for a patient with presbyopia may be even more difficult as he must learn to perceive through at least two regions. Because of the natural tendency of a patient to focus for distance vision, a patient first viewing through known presbyopia contact lenses may only experience distance vision. While such contact lenses may be suitable for the patient after the period of adjustment in which the patient learns to perceive through different portions of the lens, the initial inability of the patient to see clearly both near and far may quickly sour his opinion of the lenses and result in his unwillingness to accept the discomfort of the adjustment period. With the bivision lenses 10 having a reduced-diameter central portion, the patient can immediately see clearly objects both near and far, and the obvious correction of his presbyopia encourages him to accept any physical discomfort experienced during the adjustment period.

While no portion of the contact lens 10 is specifically designated for intermediate vision, experimental subject with advanced presbyopia report that the lenses described herein give them the ability to see not only objects at near and far distances, but give them the ability to see clearly objects at intermediate distances as well. It is believed that the junction of the central and paracentral portions 14, 18 may provide pinpoint areas of different foci which function similarly to the pinpoint optics utilized in pinhole contact lenses where light passes through tiny holes in the otherwise blacked-out lens, and because of the patient's acceptance of the lenses which immediately provide clear near and distance viewing, he learns, in time, to use the pinpoint foci in the junction region.

#### *Example*

A patient with presbyopia is determined by kera-

ometry measurement to have corneas with a 7.62 mm. base radius of curvature. The patient is near-sighted and requires a distance correction of -6.00 diopters, and a 2.50 diopter add for near vision. A series of polymethylmethacrylate lens pairs are generated, all of which are 8 mm. in diameter, have 1 mm. wide peripheral bevels with 10.50 mm. of radii of curvature, anterior surfaces with 5.26 mm. radii of curvature, posterior central portions with 6.99 mm.

- 10 radii of curvature, and posterior paracentral portion with 7.62 mm. radii of curvature. The central portions of the series of lens pairs are respectively 1, 1.5, 2, 2.5, and 3.0 mm. in diameter.

- All of the lenses fit comfortably on the patient's cornea. The lens pair with the 1.0 mm. central portions permits the patient to see near object clearly but provides no distance vision, and is therefore unacceptable. Both the lens pair with the 2.5 mm. central portions and the lens pair with the 3.0 mm. central portions permit the patient to see both near objects and distant objects, but the images are blurred and double. Both the lens pairs with the 1.5 mm. and 2.0 mm. central portions provide clear vision of both near and distant objects without blurring or double imaging. The patient reports immediate success with both the contact lens pairs with the 1.5 and 2.0 mm. central portions.

- The above results indicate that the diameter of the central distance portions of bivision contact lenses are of great importance in correcting presbyopia. To provide simultaneous near and distance vision, the central portions of the lenses should be less than 2.5 mm. in diameter and greater than 1 mm. in diameter.

- Illustrated in Figure 4 is an alternative embodiment of a contact lens according to the present invention provided between the central portion 14 and the paracentral portion 18. The annular intermediate portion 40 is generated by blending the junction between the central and paracentral portions 14, 18 with a spherical polishing tool having a radius of curvature about midway between the radii of curvature of the central and paracentral portions. The junction is polished for a very brief time to generate a narrow blend 40 having a radius of curvature generally that of the polishing tool.

- The intermediate portion 40 cooperates with the anterior surface 12 to provide a correction appropriate for viewing objects at intermediate distances. Because of the narrow width of the intermediate portion 40, it does not interfere with viewing through the central or paracentral portions 14, 18, and no blurring or double imaging is detectable.

- Although the invention has been described with regard to a preferred embodiment, it should be understood that modifications obvious to one with ordinary skill in the art may be made without departing from the scope of the invention. For example, anterior bevels may be provided to reduce the thickness of the lenses.

- Various features of the invention are set forth in the following claims.

#### CLAIMS

- having; an anterior curvature which is generally spherical, and a posterior surface having a central viewing portion, the curvature of which is generally spherical and which cooperates optically with said anterior surface to provide a distance viewing correction for the patient, and a paracentral portion, the curvature of which is generally spherical and which cooperates optically with said anterior surface to provide a near viewing correction for the patient, the improvement comprising; said central portion having a diameter greater than 1.0 mm. and less than 2.5 mm., whereby said lens provides simultaneous near and distance viewing without blurring or double imaging.
2. A lens according to Claim 1 wherein said central viewing portion is between about 1.5 and about 2.0 mm. in diameter.
3. A lens according to Claim 1 wherein said paracentral portion has a radius of curvature generally equal to that of the cornea to lie closely adjacent thereto.
4. A contact lens according to Claim 1 in which said paracentral portion serves the dual role of an optical surface and a fitting surface.
5. A contact lens substantially as hereinbefore described with reference to and as illustrated in Figures 1 to 3 or Figures 1 to 3 as modified by Figure 4 of the accompanying drawings.
6. A contact lens as set forth in the foregoing Example.

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